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November 22, 2005

Division of Dockets Management (HFM-17)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2005D-0330

Dear Sir or Madam:

Haemonetics Corporation is pleased to submit the following comments on the draft guidance document entitled "Collection of Platelets by Automated Methods", dated September 2005.

Page 5- Donor Management

The suggestion to use a post-donation count from a previous collection has not been validated to our knowledge. If the donor's platelet count is set to an artificially low value, unnecessary cycles may be drawn in an attempt to reach the target yield.

Page 6 – Collection Frequency

The restriction of the minimum platelet count with the restriction of total volume loss linked to the donor's weight has been demonstrated to provide adequate protection to the donor. Further restrictions are not necessary. We recommend that the frequency of donation should be maintained as in the present guidance and apply to all donors regardless of the quantity of platelets they donate.

Page 7 – Medical Coverage

Advances in apheresis technology have made automated collections a safe procedure. Studies of moderate and severe reactions in plateletpheresis donations demonstrate a safety profile better than that of whole blood collections.[1] The demand for platelets has forced blood centers to look at ways to increase their collections of Platelets, Pheresis, including mobile blood drives. The requirement of having a physician be on premises within 15 minutes would severely hamper a blood center's ability to collect platelets in a

[1] Rossi's Principles of Transfusion Medicine. Eds. T Simon, W Dzik, E Snyder, C Stowell, R Strauss. 3rd Edition. Lippincott Williams & Wilkins. Philadelphia. 2002. pp648-658.

2005D-0330 C4

mobile environment, and does not provide added safety for the donor. We note that the reference (reference 11 in the document) to substantiate the 15 minute on premises proposal is a proposed rule, published in 1985 that, to our knowledge, has never been finalized as a rule. The 15 minute on-premises requirement seems to be arbitrary and not substantiated by current practice.

Apheresis devices are typically operated and monitored by health care professionals that are trained in possible donor reactions and how to treat them. Most reactions are mild and donors recover quickly. Reactions can occur regardless of the components being collected, i.e., even in whole blood collections, sensitive or first-time donors can experience mild to moderate reactions. There is no reason to single out platelet collections as requiring an on-site physician. In the rare instance of a life-threatening donor reaction, an emergency response through the 911 system is the best medical option.

Page 8- B. Target Platelet Yield

The guidance suggests targets to be used to achieve certain platelet counts. As the accuracy of these targets is related to a specific device, these values may quickly become outdated and therefore should be omitted.

Page 8 and 9 – C. Hemolysis During Collection

The guidance states that if a red tinge to the plasma in the return line is noted during procedure, the center should determine if this is a result of red cell contamination or from hemolysis. To our knowledge, there is no way to determine this during a procedure. Instead, users should consult the operator's manual of the device, and, if necessary, discontinue the procedure.

Page 9 – Process Validation

The guidance recommends a pH meter to measure pH. Throughout the document, no mention is made of the temperature of the platelet product regarding pH measurement. It is known that different pH values are obtained for a platelet product measured at 20°C vs. 37°C. The guidance should be specific regarding temperature vs. pH determination.

In addition to a pH meter, a gas analyzer is also used to measure pH with reliable accuracy. This should be mentioned as an acceptable alternative.

It should also be noted that proper handling of the samples must be observed so that the pH of the samples in the test tubes reflect the actual pH of the product in the storage containers.

Page 11 – Sample Size

The guidance appears to allow 2 sample sizes for performance qualifications; 60 units or 93 units. The acceptance criteria are 0 failures in 60 samples, or 1 failure in 93 samples with respect to yield, pH and residual WBC count and component recovery. We interpret this to mean that if, for example, a center encounters a failure at test number 40, it should continue with 93 samples and encounter no further failures in order to meet the acceptance criteria. However, the guidance states the opposite, that if a center tests 60 samples and encounters a failure, it should not continue with 33 more samples. This is inconsistent and confusing.

Page 11 – Testing of Components

The guidance suggests testing components during the first, middle and end of the dating period. We believe this is excessive testing. Testing should be done at day 1 and expiration only. This gives an accurate picture of the quality of the product. Testing during the middle of the dating period is unnecessary.

Page 12 – Testing of Components

The guidance addresses bacterial testing of products with a 99%/99% binomial distribution. It does not specify whether this applies to 5 or 7 day storage of platelets. There currently is no regulatory requirement to test 5 day platelets for bacterial contamination. There is also no commercially available test kit that is cleared for general bacterial release testing. The requirement to test all platelet products for bacterial contamination by an FDA-cleared method is unreasonable and burdensome.

The capacity for the current filters to meet the requirement of >85% recovery is unknown as this has not been a requirement that has been imposed as part of the premarket notification process.

VII. Quality Assurance (QA) and Monitoring

Page 13– Introduction

The introductory paragraph of this section states that whether a process is operating in a state of control is determined by analyzing the day-to-day process. It is not clear what this statement means. On page 18, a daily component specification check includes volume determination, residual WBC counts if there is no automated leukoreduction methodology, hematocrit determination if there are visible red cells in the product, and bacterial contamination testing. Are these items intended to satisfy the daily monitoring of the process?

Residual leukocyte count is not appropriate as a daily check if the center is using an FDA cleared filter. This is more appropriate as a monthly quality control parameter.

Hematocrit determination of visibly contaminated product is an abnormal occurrence and is not appropriate as a process monitoring parameter.

Bacterial contamination monitoring is also not appropriate as a daily process monitoring parameter because, as acknowledged in the guidance, bacterial contamination is frequently the result of asymptomatic bacteremia or the result of improper venipuncture preparation.

We suggest that volume determination and platelet concentration are appropriate parameters for monitoring process capability.

Page 15 - RBC Loss

The guidance suggests that the extracorporeal red cell volume supplied by the manufacturer of the automated blood cell separator should be used to calculate the volume of RBCs remaining in the apheresis collection set after the collection of platelets. However, our cleared manual does not define this value.

Page 16 - Labeling

The guidance states that the volume range reported on the label must be within reasonable limits. This should be further defined as it is open to interpretation.

Page 18 - Component testing

The guidance suggests that platelet counts should be completed at the conclusion of each appropriate phase of manufacturing. This requirement is excessive as written, in that several platelet counts would need to be completed throughout the process.

Page 19 - QC Monitoring

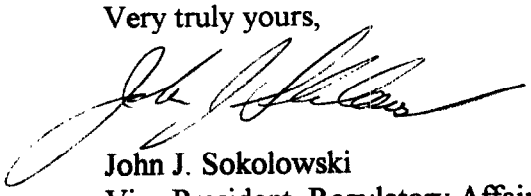
The guidance states that an alternative method can be used to scan statistics, but as this may be open to interpretation by inspectors who may not have knowledge of statistical process control, an alternative method should be provided that uses a continuous data model. When scan statistics is used, this does not allow the site to monitor the process and make corrections prior to the failure.

Page 24 - CBE-30

The guidance document suggests that any upgrades provided by the manufacturer require a CBE-30 to be submitted. It should be clarified that if the update to the device has been subject to the premarket notification process, then it has met the requirement of substantial equivalence. Therefore, there is only a small risk that the change would impact the "identity, strength, quality, purity, and potency of the product as they relate to the safety and or effectiveness of the product...." In some cases, including the change in the annual report may be sufficient.

Thank you for the opportunity to comment on this draft guidance.

Very truly yours,



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